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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,781	02/06/2001	Jacques Theze	202930US0CIP	3255
22850	7590	06/08/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/776,781	<b>Applicant(s)</b> THEZE ET AL.	
	<b>Examiner</b> Prema M Mertz	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16, 18-32 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16, 19-26, 28-32, 38-41 is/are rejected.
- 7) ☒ Claim(s) 18 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/2004 has been entered.
2. Claims 1-15, 17, 33-37, have been canceled previously. Original claims 18, 27-30, 31-32, 38-41, and amended claims 16, 19-20, 21-25, (3/5/2004) are pending and under consideration in the instant application.

#### *Claim rejections-35 USC § 112, first paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 19-25, 28-32, 38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16, line 3, for example, recites "competes with IL-2 for IL-2R  $\beta$ -chain binding" which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

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The specification page 39, discloses:

Studies were performed either with a murine cell line transfected by human IL-2R $\beta$  gene (TS1 $\beta$ ) or with an IL-2 dependant human leukemic cell line (Kit 225 from Dr. T. HOR1).

IP130 stimulates the proliferation of TS1 $\beta$  in the absence of IL-2. In the presence of IL-2 a strong synergy is observed with the peptide. Both activities are obtained at comparable concentrations (IC-50  $\mu$ M).

IP130 acts only on cell lines expressing human IL-2R $\beta$ . This is in agreement with previous studies showing that murine IL-2R $\beta$  does not bind IL-2 (CHASTAGNER et al. 1996, Eur. J. Immunol. 26:201-6). Consequently, classical murine cell lines (C30-1, CTLL, HT-2, ....) usually used to assay IL-2 activity remains insensitive to IP130 effects. Furthermore anti-human IL-2R $\beta$  blocking mAb neutralizes the effects of IP130.

The specification does not disclose the specific limitation "competes with IL-2 for IL-2R  $\beta$ -chain binding". In fact the specification on page 39, lines 22-24, discloses that in the presence of IL-2 a strong synergy is observed with the IP130 peptide. Furthermore, the peptide of SEQ ID NO:6 is the IP 131 peptide disclosed on page 5, lines 26-29, of the specification. This rejection can only be obviated by reciting the specific limitation for which there is support in the instant specification.

Claims 19-25 are rejected under 35 USC § 112, first paragraph because they also recite the new matter "competes with IL-2 for IL-2R  $\beta$ -chain binding". Claims 26, 28-32, 38-41 are rejected under 35 USC § 112, first paragraph insofar as they depend on the above claims for their limitations.

***Claim rejections-35 USC § 112, second paragraph***

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4. Claims 16, 19-26, 28-32, 38-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite because it recites “ which competes with IL-2 for IL-2R  $\beta$ -chain binding and/or lymphocyte stimulatory activity”. It is unclear how the peptide could compete with IL-2 and if it does not bind, then how can the peptide stimulate lymphocytes? It is suggested that the claim be amended to recite the specific activity of the peptide for which there is a basis in the instant specification.

Claims 19-25 are rejected as vague and indefinite because they recite the limitation “ which competes with IL-2 for IL-2R  $\beta$ -chain binding and/or lymphocyte stimulatory activity”.

Claims 19-26, line 1, are vague and indefinite because they recite, “is an amino acid sequence” rather than “which consists of an amino acid sequence”, since an amino acid sequence is a property of a peptide.

Claims 22-25, line 3, are vague and indefinite because they recite, “which competes with IL-2...” rather than “which peptide competes with IL-2...”.

Claims 24 and 25, line 3, are vague and indefinite because they recite, “such that” rather than the conventional “so that”.

Claims 28-32, 38-41, are vague and indefinite insofar as they depend on the above claims for their limitations.

### ***Conclusion***

No claim is allowed.

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Claims 18 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
May 25, 2004